Complete Summary

GUIDELINE TITLE

Management of initial gout in adults.

BIBLIOGRAPHIC SOURCE(S)

The University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program. Management of initial gout in adults. Austin (TX): University of Texas at Austin, School of Nursing; 2009 May. 9 p. [23 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

July 30, 2009 - Colchicine (Colcrys): The U.S. Food and Drug Administration (FDA) notified healthcare professionals of the approval of the first single-ingredient oral colchicine product, Colcrys, for the treatment of familial Mediterranean fever (FMF) and acute gout flares and of two previously uncharacterized safety concerns associated with the use of colchicine. FDA has included important safety considerations in the approved prescribing information to assure safe use of Colcrys and is providing background information, a data summary and recommendations in this alert.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

DISEASE/CONDITION(S)

Acute gout

GUIDELINE CATEGORY

Management Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Nursing
Nutrition
Podiatry
Rheumatology

INTENDED USERS

Advanced Practice Nurses Dietitians Nurses Physician Assistants Physicians Podiatrists

GUIDELINE OBJECTIVE(S)

To present a national guideline on the management of acute gout in adults

TARGET POPULATION

Adults in the general population diagnosed with or with symptoms indicative of gout (acute attack)

INTERVENTIONS AND PRACTICES CONSIDERED

Management/Treatment

- 1. Pharmacologic management
 - Non-steroidal anti-inflammatory drugs (NSAIDs)
 - Colchicine
 - Corticosteroids (systemic or intra-articular)
 - Vitamin C
 - Discontinuation of drugs increasing urate level
- 2. Non-pharmacologic management

- Diet, including:
 - Low purine diet
 - Low alcohol diet
 - Low fructose diet
 - Low-fat dairy diet
 - Coffee
- Ice
- Rest
- Comorbidity management

MAJOR OUTCOMES CONSIDERED

- Efficacy of treatment
- Adverse effects of medications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were conducted via electronic databases including UpToDate, Cochrane Library, PubMed, CINAHL, and MEDLINE using keywords: "allopurinol", "colchicine", "corticosteroids", "diet", "febuxostat", "gout", "initial", and "treatment."

NUMBER OF SOURCE DOCUMENTS

5

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor).

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the

individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations according to one of five classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms).

- **A**. The USPSTF strongly recommends that clinicians provide the service to eligible patients. The USPSTF found good evidence that the service improves important health outcomes and concludes that benefits substantially outweigh harms.
- **B**. The USPSTF recommends that clinicians provide this service to eligible patients. The USPSTF found at least fair evidence that the service improves important health outcomes and concludes that benefits outweigh harms.
- **C.** The USPSTF makes no recommendation for or against routine provision of the service. The USPSTF found at least fair evidence that the service can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.
- **D**. The USPSTF recommends against routinely providing the service to asymptomatic patients. The USPSTF found at least fair evidence that the service is ineffective or that harms outweigh benefits.

I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing the service. Evidence that the service is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Strength of recommendations (A, B, C, D, I) and quality of evidence (good, fair, poor) are defined at the end of the "Major Recommendations" field.

Clinical Recommendation

Pharmacological

1st Line—Non-steroidal Anti-inflammatory Drugs (NSAIDs)

- Naproxen 500 mg twice a day (BID), Indocin 50 mg orally (PO) three times a day (TID), or comparable dose of other NSAID. Most effective if initiated within 24 hours of onset of attack (Janssens et al., 2008; Rubin et al., 2004; Schumacher et al., 2002; Zhang et al., 2006).
- Caution should be used in patients with concomitant anticoagulant use and cardiovascular disease.
- Contraindications include patients with gastrointestinal (GI) ulcers or bleed and renal insufficiency. (**Grade B, Evidence Fair**)

2nd Line—Colchicine

- Colchicine 1-1.2 mg PO x 1 dose followed by 0.5-0.6 mg every (q) 2-3 hrs until relief of gouty inflammation or toxicity effects of nausea, vomiting, diarrhea limits further use. Maximum dosage 6 mg. Most effective if given during the first 12 to 24 hours of an acute attack (Ahern et al., 1987).
- Alternative dosage is colchicine 0.5 mg PO BID-TID to reduce adverse side effects (Morris, Varughese, & Mattingly, 2003; Zhang et al., 2006)

- Contraindications include patients with serious GI, renal, hepatic, or cardiac disorders, and blood disorders.
- Colchicine should not be given intravenously (IV) due to the potential for lifethreatening adverse effects. (**Grade B, Evidence Fair**)

3rd Line—Corticosteroids

- Systemic corticosteroids Prednisolone 30-35 mg PO daily x 5 days or triamcinolone acetonide 60 mg intramuscularly (IM) x 1 dose. Indicated in patients who have contraindications to NSAIDS and colchicine and also have polyarticular disease (Janssens et al., 2008; Man et al., 2007). (Grade B, Evidence Fair)
- Intra-articular corticosteroids Indicated if only 1-2 joints is involved. Triamcinolone acetonide 8-10 mg intra-articular or equivalent doses of depomethylprednisolone. Joint infection must be ruled out prior to considering corticosteroid injection (Schlesinger, 2008). (Grade B, Evidence Fair)

Adjunct—Pharmacological

- Initiate Vitamin C 500mg PO every day (Gao et al., 2008; Huang et al., 2005) (**Grade A, Evidence Good**)
- Do not start new xanthine oxidase inhibitor therapy such as allopurinol or febuxostat during acute phase; initiate 4 to 6 weeks after an acute attack. If on prophylaxis therapy at the time of an acute attack, continue therapy (Becker, 2008; Eggebeen, 2007). (Grade B, Evidence Fair)
- Discontinue drugs associated with gout when possible (Eggebeen, 2007; Montgomery, 2008).
 - Antileukemic agents
 - Aspirin
 - Cyclosporine
 - Epinephrine
 - Ergotamine
 - Ethacrvnic acid
 - Ethanol
 - Loop diuretics (furosemide)
 - Nicotinic acid
 - Pyrazinamide
 - Salicylates
 - Thiazide diuretics

(Grade I, Evidence Poor)

• Control of non-gout chronic disease processes: obesity, diabetes mellitus (DM), and metabolic syndrome (Eggebeen, 2007; Montgomery, 2008). (Grade B, Evidence Fair)

Nutritional

Low purine diet—Avoid red meats, seafood (Choi & Curhan, 2008; Choi, Liu, & Curhan, 2005; Hak & Choi, 2008; Williams, 2008). (Grade A, Evidence Good)

- Low fructose diet, especially avoiding sugar-sweetened soft drinks (Choi & Curhan, 2007; Hak & Choi, 2008). (Grade A, Evidence Good)
- Avoid alcohol consumption (Choi & Curhan, 2008; Hak & Choi, 2008; Williams, 2008). (Grade A, Evidence Good)
- Low-fat dairy diet (Choi & Curhan, 2008; Choi, Liu, & Curhan, 2005; Hak & Choi, 2008; Williams, 2008). (Grade A, Evidence Good)
- Encourage intake of 2 cups of coffee daily (Choi & Curhan, 2007). (Grade A, Evidence Good)

Adjunct Non-Pharmacological

- Ice therapy (Dorwart, Hansell, & Schumacher, 1974; Schlesinger, 2006; Schlesinger et al., 2002). (Grade B, Evidence Fair)
- Avoid heat therapy (Dorwart, Hansell, & Schumacher, 1974; Schlesinger, 2006). (Grade B, Evidence Fair)
- Rest of affected joint (Agudelo, Schumacher, & Phelps, 1972; Jordan et al., 2007). (Grade B, Evidence Fair)

Definitions:

Quality of Evidence (Based on U.S. Preventive Services Task Force [USPSTF] Ratings)

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence of health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their designs or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Grading of Recommendations (Based on USPSTF Ratings)

- **A**. The USPSTF strongly recommends that clinicians provide the service to eligible patients. The USPSTF found good evidence that the service improves important health outcomes and concludes that benefits substantially outweigh harms.
- **B**. The USPSTF recommends that clinicians provide this service to eligible patients. The USPSTF found at least fair evidence that the service improves important health outcomes and concludes that benefits outweigh harms.
- **C**. The USPSTF makes no recommendation for or against routine provision of the service. The USPSTF found at least fair evidence that the service can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

- **D**. The USPSTF recommends against routinely providing the service to asymptomatic patients. The USPSTF found at least fair evidence that the service is ineffective or that harms outweigh benefits.
- I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing the service. Evidence that the service is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for selected recommendations (see "Major Recommendations").

The recommendations were based primarily on a comprehensive review of published reports. In cases where the data did not appear conclusive, recommendations were based on the consensus opinion of the group.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Pain reduction and appropriate management of initial gout

POTENTIAL HARMS

Adverse Effects of Medications

- Non-steroidal anti-inflammatory drugs (NSAIDs) are associated with gastrointestinal side effects. Caution should be used in patients with concomitant anticoagulant use and cardiovascular disease.
- Colchicine is associated with nausea, vomiting, and diarrhea.
- Systemic corticosteroids can cause adverse effects to the endocrine system.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Contraindications to *non-steroidal anti-inflammatory drugs (NSAIDs)* include patients with gastrointestinal (GI) ulcers or bleeding and renal insufficiency.
- Contraindications to *colchicine* include patients with serious GI, renal, hepatic, or cardiac disorders, and blood disorders. Colchicine should not be given intravenously (IV) due to the potential for life-threatening adverse effects.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009 May

GUIDELINE DEVELOPER(S)

University of Texas at Austin School of Nursing, Family Nurse Practitioner Program - Academic Institution

SOURCE(S) OF FUNDING

University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available.

Print copies: Available from the University of Texas at Austin, School of Nursing. 1700 Red River, Austin, Texas, 78701-1499

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on February 5, 2010. The information was verified by the guideline developer on April 26, 2010.

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